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Sheet 1

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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of 1

Complete if Known					
Application Number	10/660,069				
Filing Date	09/11/2003				
First Named Inventor	HAYES et al.				
Art Unit	<del>1646-</del> 1647				
Examiner Name	Sandra Wegert				
Attorney Docket Number	5853-283				

				DOCUMENTS	
Examiner initials*	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	<u> </u>	Number-Kind Code <sup>2 (# known)</sup>			Figures Appear
/SLW/		US- 5,118,606	06/02/1992	Lynch et al.	
/SLW/		US- <sub>5,536,639</sub>	07/16/1996	Siman et al.	
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		Country Code <sup>3</sup> Number <sup>4</sup> 'Kind Code <sup>8</sup> (if known)  MM-DD-YYYY	, pp. 100 100 100 100 100 100 100 100 100 10	Or Relevant Figures Appear	ŀ	
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Examiner Signature	/Sandra Wegert/	Date Considered	05/14/2007

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STA	STATEMENT BY APPLICANT				ICANT	First Named Inventor	HAYES et al.	
	// /-	A 26 M2N	, chaote ac	nocaccan	vi ·	Art Unit	<del>1646</del> 1647	
	(Use as many sheets as necessary)				"	Examiner Name	Sandra Wegert	
Sheet	14	2	of	21	2	Attorney Docket Number	5853-283	

Examiner	Cite	NON PATENT LITERATURE DOCUMENTS  Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of	T
Initials*	No.1	the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T.²
/SLW/		GIZA et al., "The Neurometabolic Cascade of Concussion," Journal of Athletic Training, 36:228-235, 2001.	
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Examiner		Date	05/44/0007
Signature	/Sandra Wegert/	Considered	05/14/2007

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Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

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Complete if Known						
Application Number	10/660,069					
Filing Date	September 11, 2003					
First Named Inventor	Ronald L. Hayes					
Art Unit	1647					
Examiner Name	Sandra Wegert					
Attorney Docket Number	UF-530XT					

	-		U.S. PATENT DO	OCUMENTS	
Examiner Initials*	Cite No. 1	Document Number Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/SLW/	U1	US 5,536,639	07-16-1996	Siman, et al.	all
/SLW/	U2	US 5,118,606	06-02-1992	Lynch, et al.	all
	U3				
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. 1	Foreign Patent Document  Country Code 3 - Number 4 - Kind Code 5 (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	1*
/SLW/	F1	WO 95/26506	10-05-1995	Cephalon, Inc.	ALL	
	F2					
	F3					
	F4					

Examiner	/Sandra Wegert/	Date	05/44/0007
Signature	Journal Wegelv	Considered	05/14/2007

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Transation is attached.

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	ite for form 1449B/PTO		OCUPE	Application Number	10/660,069
-	RMATION D			Filing Date	September 11, 2003
STA	STATEMENT BY APPLICANT			First Named Inventor	Ronald L. Hayes
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(use as many sheets as necessary)				Examiner Name	Sandra Wegert
Sheet	2	of	3	Attorney Docket Number	UF-530XT

	NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*			T²				
/SLW/	R1	PIKE, BRIAN R., et al.: "Accumulation of non-erythroid alphall-spectrin and calpain-cleaved alphall-spectrin breakdown products in cerebrospinal fluid after traumatic brain injury in rats", <i>Journal of Neurochemistry</i> , September 2001, pp 1297-1306, Vol. 78, No. 6.					
/SLW/	R2	NATH, RATHNA, et al.: "Non-erythroid alpha-spectrin breakdown by calpain and interleukin 1beta-converting-enzyme-like protease(s) in apoptic cells: contributory roles of both protease families in neuronal apoptosis", Biochemistry Journal, November 1, 1996, pp. 683-690, Vol. 319.					
/SLW/	R3	LI, ZHAOZHAO, et al.: "Peptide alpha-Keto Ester, alpha-Keto Amide, and alpha-Keto Acid Inhibitors of Calpains and Other Cysteine Proteases", Journal of Medicinal Chemistry, October 29,1993, pp. 3472-80, Vol. 36, No. 22.					
/SLW/	YOKOTA, M., et al.: "Three distinct phases of fodrin proteolysis induced in postischemic						
/SLW/	NATH, RATHNA, et al.: "Development and characterization of antibodies specific to caspase-3- produced alpha II-spectrin 120 kDa breakdown product; marker for neuronal apoptosis".						
/SLW/	R6	PIKE, BRIAN R., et al.: "Regional calpain and caspase-3 proteolysis of alpha-spectrin after traumatic brain injury", NeuroReport, August 3, 1998, pp. 2437-42, Vol. 9, No. 11.					
/SLW/	R7	ZHAO, X., et al.: "Maitotoxin Induces Calpain But Not Casepase-3 Activation and Necrotic Cell Death in Primary Septo-Hippocampal Cultures", Neurochemical Research, 1999, pp. 371-382, Vol. 24, No. 3.					
/SLW/	R8	PIKE, BRIAN R., et al.: "Temporal Relationships Between De Novo Protein Synthesis, Calpain and Calpase 3-like Protease Activation, and DNA Fragmentation During Apoptosis in Septo-Hippocampal Cultures", Journal of Neuroscience Research, 1998, pp. 505-520, Vol. 52.					
/SLW/	R9	GIZA, CHRISTOPHER C., et al.: "The Neurometabolic Cascade of Concussion", Journal of Athletic Training, September 2001, pp. 228-235, Vol. 36, No. 3.					
/SLW/	R10	MCGINNIS, KIM M., et al., "Alterations of Extracellular Calcium Elicit Selective Modes of Cell Death and Protease Activation in SH-SY5Y Human Neuroblastoma Cells", Journal of Neurochemistry, 1999, pps. 1853-63, Vol. 72, No. 5, Lippincott Williams & Wilkins, Inc., Philadelphia, PA.					

1	Examiner	/Sandra Wegert/	Date	05/44/0007	Ì
	Signature	Touridia Wogord	Considered	05/14/2007	ı

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		for form 1449B/P			une	Application Number	10/660,069	
INFORMATION DISCLOSURE						Filing Date	September 11, 2003	
	STATEMENT BY APPLICANT			ANT	First Named Inventor	Ronald L. Hayes		
	(	as many shee	to oo o		)	Group Art Unit	1647	
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	Sheet	3	0		3	Attorney Docket Number	UF-530XT	

	NON PATENT LITERATURE DOCUMENTS						
Examiner Cite No. 1		Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.					
/SLW/	R1	NATH, RATHNA, et al.: "Activation of apoptosis-linked caspase(s) in NMDA-injured brains in neonatal rats", Neurochemistry International, 2000, pp. 119-126, Vol. 36.					
/SLW/	R2	BARTUS, RAYMOND T., et al. "Time-Related Neuronal Changes Following Middle Cerebral Artery Occlusion: Implications for Therapeutic Intervention and the Role of Calpain," Journal of Cerebral Blood Flow and Metabolism", November 1995, pp. 969-79, Vol. 15, No. 6, Lippincott-Raven Publishers, Philadelphia, PA.					
/SLW/	R3	Supplementary Partial European Search Report					
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Examiner Signature	/Sandra Wegert/	Date Considered	05/14/2007
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**Application Number** 10/660,069 September 11, 2003 **Filing Date** First Named Inventor Ronald L. Hayes 1647 **Group Art Unit Examiner Name** <u>Sandra Wegert</u> **Attorney Docket Number UF-530XT** 

Complete if Known

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*			T²			
/SLW/	R1	WANG, KEVIN K.W., et al., "Simultaneous Degradation of αII and βII-Spectrin by Caspase 3 (CPP32) in Apoptotic Cells", <i>The Journal of Biological Chemistry</i> , August 28, 1998, pp. 22490-22497, Vol. 273, No. 35, The American Society for Biochemistry and Molecular Biology, Inc., U.S.A.				
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Examiner	/Sandra Wegert/	Date	05/14/2007
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